4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1584]

Authorization of Emergency Use of Certain Medical Devices During COVID-19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the issuance of Emergency Use Authorizations (EUAs) (the Authorizations) for certain medical devices related to the Coronavirus Disease 2019 (COVID-19) public health emergency. FDA has issued the Authorizations listed in this document under the Federal Food, Drug, and Cosmetic Act (FD&C Act). These Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the February 4, 2020, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves the virus that causes COVID-19, and the subsequent declarations on February 4, 2020, March 2, 2020, and March 24, 2020, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19, personal respiratory protective devices, and medical devices, including alternative products used as medical devices, respectively, subject to the terms of any authorization issued under the FD&C Act. These Authorizations, which include an explanation of the reasons for issuance, are listed in this document, and can be accessed on FDA's website from the links indicated.

DATES: These Authorizations are effective on their date of issuance.

ADDRESSES: Submit written requests for single copies of an EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993-0002, 301-796-8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a biological, chemical, radiological, or nuclear agent or agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including

personnel operating under the authority of title 10 or title 50 of the U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces[1]; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. 247d-6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the *Federal Register* a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on the internet website of FDA. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under section 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, or 360e) or

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA[2] concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied. No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

II. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet and can be accessed from https://www.fda.gov/emergency-

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

III. The Authorizations

Having concluded that the criteria for the issuance of the following Authorizations under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of the following products for diagnosing, treating, or preventing COVID-19 subject to the terms of each Authorization. The Authorizations in their entirety, including any authorized fact sheets and other written materials, can be accessed from the FDA web page entitled "Emergency Use Authorization," available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization. The lists that follow include Authorizations issued from September 11, 2021, through January 24, 2022, and we have included explanations of the reasons for their issuance, as required by section 564(h)(1) of the FD&C Act. In addition, the EUAs that have been reissued can be accessed from FDA's web page: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

FDA is hereby announcing the following Authorizations for molecular diagnostic and antigen tests for COVID-19, excluding multianalyte tests:[3]

- Life Sciences Testing Center's Life Sciences Testing Center COVID-19 Test, issued September 22, 2021;
- ANP Technologies, Inc.'s NIDS COVID-19 Antigen Rapid Test Kit, issued September 24, 2021;
- Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute's SelfCheck cobas SARS-CoV-2 Assay, issued September 29, 2021;

[3] As set forth in the EUAs for these products, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the products may be effective in diagnosing COVID-19, and that the known and potential benefits of the products, when used for diagnosing COVID-19, outweigh the known and potential risks of such products; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

- ACON Laboratories, Inc.'s Flow*flex* COVID-19 Antigen Home Test, issued October 4, 2021;
- Xtrava Health's SPERA COVID-19 Ag Test, issued October 12, 2021;
- LMSI, LLC's (d/b/a Lighthouse Lab Services) CovidNow SARS-CoV-2 Assay, issued October 14, 2021;
- Celltrion USA, Inc.'s Celltrion DiaTrust COVID-19 Ag Home Test, issued October 21, 2021;
- Detect, Inc's Detect Covid-19 Test, issued October 28, 2021;
- Talis Biomedical Corporation's Talis One COVID-19 Test System, issued November 5, 2021;
- iHealth Labs, Inc.'s iHealth COVID-19 Antigen Rapid Test, issued November 5, 2021;
- Meridian Bioscience, Inc.'s Revogene SARS-CoV-2, issued November 9, 2021;
- InBios International Inc.'s SCoV-2 Ag *Detect* Rapid Self-Test, issued November 22, 2021;
- Nano-Ditech Corp.'s Nano-Check COVID-19 Antigen Test, issued December 6, 2021;
- UCSD BCG EXCITE Lab's UCSD EXCITE COVID-19 Test, issued December 17, 2021;
- SD Biosensor, Inc.'s COVID-19 At-Home Test, issued December 24, 2021;
- Siemens Healthineers' CLINITEST Rapid COVID-19 Antigen Self-Test, issued December 29, 2021;
- Premier Medical Laboratory Services' PMLS SARS-CoV-2 Assay, issued January 7, 2022;
- iHealth Labs, Inc.'s iHealth COVID-19 Antigen Rapid Test Pro, issued January 14, 2022;
- Maxim Biomedical, Inc.'s MaximBio ClearDetect COVID-19 Antigen Home Test, issued January 19, 2022; and
- Mammoth Biosciences, Inc.'s DETECTR BOOST SARS-CoV-2 Reagent Kit, issued January 21, 2022.

FDA is hereby announcing the following Authorizations for serology tests:[4]

- EUROIMMUN US, Inc.'s EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG), issued October 4, 2021;
- InBios International, Inc.'s SCoV-2 *Detect* Neutralizing Ab ELISA, issued October 22, 2021.

FDA is hereby announcing the following Authorizations for multianalyte in vitro diagnostics:

- Laboratory Corporation of America's Labcorp SARS-CoV-2 & Influenza A/B Assay, issued September 30, 2021;[5]
- PerkinElmer, Inc.'s PKamp Respiratory SARS-CoV-2 RT-PCR Panel 1, issued October 6, 2021;[6] and
- Applied BioCode, Inc.'s BioCode CoV-2 Flu Plus Assay, issued December 15, 2021[7]

FDA is hereby announcing the following Authorizations for other medical devices:

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[4] As set forth in the EUAs for these products, FDA has concluded that: (1) SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the products may be effective in diagnosing recent or prior infection with SARS-CoV-2 by identifying individuals with an adaptive immune response to the virus that causes COVID-19, and that the known and potential benefits of the products when used for such use, outweigh the known and potential risks of the products; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

[5] As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID-19 through the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus RNA and that the known and potential benefits of the product when used for diagnosing COVID-19, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[6] As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID-19, through the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A, influenza B, and/or RSV virus RNA, and that the known and potential benefits of the product when used for diagnosing COVID-19, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[7] As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID-19, through the simultaneous qualitative detection and differentiation of RNA from SARS-CoV-2, influenza A virus, influenza B virus, and/or RSV, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

- Quest Diagnostics Infectious Disease, Inc.'s Quest Diagnostics Collection Kit for COVID-19, issued October 8, 2021;[8]
- Audere's HealthPulse@home, issued November 30, 2021;[9]

In addition, on September 23, 2021, FDA issued a letter to Developers of Certain Molecular, Antigen and Serology In Vitro Diagnostics (IVDs) Authorized for Emergency Use for Coronavirus Disease 2019 (COVID-19) as of Today's Date (September 23, 2021) for Establishing additional Conditions of Authorization for the EUAs of Certain Molecular, Antigen and Serology IVDs related to viral mutations.[10]

Dated: March 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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[8] As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID-19 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the collected human specimen, and that the known and potential benefits of the product when used for such use, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[9] As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID-19 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the collected human specimen, and that the known and potential benefits of the product when used for such use, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[10] FDA concluded that establishing additional conditions on the EUAs within the scope of the letter is appropriate to protect the public health or safety and revised all such EUAs pursuant to Section 564(g)(2)(C) of the FD&C Act to establish the three additional conditions set forth in the letter as permitted by Section 564(e) of the FD&C Act.